IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

UNITED STATES OF AMERICA et al., EX REL. SCARLETT LUTZ and KAYLA WEBSTER,

Plaintiffs/Relators,

v.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Defendant.

C/A No. 9:14-cv-3699-RMG

ORAL ARGUMENT REQUESTED

RELATORS MEMORANDUM IN OPPOSITION TO DEFENDANT LABORATORY CORPORATION OF AMERICA HOLDINGS' MOTION TO DISMISS FOURTH AMENDED QUI TAM COMPLAINT

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I. INTRODUCTION

The Court is fully aware of the kickback scheme hatched by LaTonya Mallory, Floyd Calhoun ("Cal") Dent, Robert Bradford ("Brad") Johnson, Mallory's company, Health Diagnostic Laboratory ("HDL"), and Singulex, Inc. ("Singulex). That scheme was the focus of the Government's settlements with HDL and Singulex, a jury verdict against Mallory, Dent, and Johnson, and a $111 million judgment entered by the Court. FAC ¶¶ 37–45.

What this Court has not yet adjudicated is Laboratory Corporation of America Holdings' ("LabCorp's") own kickback violations and its contribution to the HDL and Singulex kickback fraud. Relators' Fourth Amended Complaint ("FAC") exposes LabCorp's critical role in three related fraudulent schemes, causing the submission of false HDL and/or Singulex claims, the submission of LCAs own false claims, and LabCorp's retention of monies which should have been repaid to the government.

First, from at least early 2010 through mid-2014, LabCorp conspired to cause and/or caused the submission of kickback-tainted claims by HDL, and Singulex. *Id.* ¶ 1, n. 1. LabCorp knew that HDL and Singulex were providing illegal kickbacks, but knowingly provided free phlebotomy (blood draws and processing) for blood samples referred by LabCorp's customer physicians to HDL and Singulex. *Id.* ¶ 5. By providing blood draws and processing services, LabCorp physically participated in ensuring that the referrals from physicians receiving kickbacks reached HDL and Singulex.

Second, LabCorp provided inducements (free phlebotomy services for HDL and Singulex tests) to its customer physicians in exchange for referrals of other tests to LabCorp. *Id.* ¶ 7. As a result, LabCorp also submitted its own false claims, which were tainted by its inducements. *Id.*

Third, LabCorp then concealed its involvement in these fraud schemes by submitting misleading requests for fraud alerts to the Office of Inspector General ("OIG") — turning on its

co-conspirators while remaining silent on its own critical role in the HDL and Singulex fraud. *Id.* ¶ 16.

In its Motion to Dismiss (the "Motion") LabCorp attempts to turn its duplicity to virtue – arguing that it cannot be liable for its active participation in the HDL and Singulex schemes because it requested fraud alerts from the Department of Health and Human Services Office of Inspector General ("OIG"). Motion p. 1. This argument ignores the reality that LabCorp pursued simultaneous courses of action – participating in a fraudulent scheme with HDL and Singulex, while reporting the same scheme in order to conceal its own involvement and eliminate the competitive advantage that HDL and Singulex gained from paying kickbacks. LabCorp recognizes that Relators' allegations must be taken as true for purposes of its Motion, yet it attempts to argue that LabCorp's *incomplete and misleading* reporting of its co-conspirators' fraud renders Relators' allegation legally defective. *Id.* at 23. In reality, LabCorp's misleading reports *adds* bases for its FCA liability.

LabCorp's Motion does not seek dismissal of Relators' claims based on the Anti-Kickback Statute ("AKS"). *See, generally* Motion. Accordingly, even if the Court grants LabCorp's Motion, Relators Count I claims rooted in an AKS theory will remain viable. LabCorp seeks to dismiss all but Relators' AKS claims because: (1) Relators cannot state a claim against LabCorp for submitting or causing the submission of medically unnecessary tests because LabCorp does not determine medical necessity; (2) Relators' reverse false claims fail because the claims are duplicative of direct claims and the claims fail to meet Rule 9(b)'s particularity requirement; (3) Relators' state law claims must be dismissed because Relators lack standing as "interested persons," and the claims fail to meet Rule 9(b)'s particularity requirement; and (4) Relators fail to

adequately allege a conspiratorial agreement or a specific intent to defraud the government. As explained in the Argument section of this response, each argument fails.

Finally, LabCorp notes that the Government "investigated these allegations and declined to intervene, and LabCorp looks forward to refuting Relators' allegations at the appropriate time." Motion p. 2. To the extent LabCorp argues that the Government's declination is based on an assessment of the merits, LabCorp is incorrect. No inference about the merits of a relator's allegations may be drawn from the Government's decision not to intervene in a *qui tam* matter. *See United States ex rel. Berge v. Bd. Of Trustees*, 104 F.3d 1453, 1458 (4th Cir. 1997).[1] Furthermore, when the Government declines to intervene, it still stands to receive 70–75% of the total recovered by Relators. 31 U.S.C. § 3730(d)(2).

II. STATEMENT OF FACTS

A. The Parties

LabCorp is a publically traded, for-profit company that provides clinical laboratory testing and phlebotomy services to doctor's offices and other health care entities throughout the United States, including in California and Illinois. FAC ¶ 58.

Relator Kayla Webster is a registered nurse who worked for Dr. Miller from 2008 through July 2013. *Id.* ¶¶ 51, 54. Relator Webster observed Dr. Miller referring patients to LabCorp, HDL,

[1] Here, counsel for the Government has represented to counsel for Relators that it declined to intervene based on its limited resources and not because the claims lack merit. Courts across the country understand and endorse the common-sense notion that the Government declines intervention for reasons completely unrelated to the merits of an underlying matter. *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n. 17 (11th Cir. 2006) (noting that courts "do not assume that . . . it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator's allegations for fraud to be without merit."); *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008) (the "simple fact that the government did not intervene has no probative value and is not relevant."); *see also U.S. ex rel. Chandler v. Cook Cty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003) ("The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney.").

and Singulex. *Id.* ¶ 54. She also reviewed patient lab test results from these providers. *Id.* As a result of her work in Dr. Miller's office, Relator Webster observed LabCorp's conduct, including its marketing efforts and practices, the inducements offered by LabCorp, LabCorp's involvement in the HDL/Singulex kickback scheme, and the resultant false billings to both Government healthcare programs and private insurers. *Id.* ¶¶ 55–56. For example, Relator Webster observed LabCorp place an in-office phlebotomist ("IOP") in Dr. Miller's office in early 2011. *Id.* ¶ 255. Relator Webster personally observed LabCorp's employee performing services that were the responsibility of Dr. Miller's staff. *Id.* ¶¶ 259–61.[2]

Relator Scarlett Lutz owns and operates Palmetto Billing Services in Florence, South Carolina. *Id.* ¶ 48. From March of 2011 until September of 2011, Relator Lutz provided billing services to Dr. Lloyd Miller, a primary care physician in Florence, South Carolina. *Id.* ¶ 49. Relator Lutz learned of LabCorp's involvement in the HDL/Singulex scheme, as well as LabCorp's own false claims for clinical laboratory testing, while providing billing and collection services to Dr. Miller. *Id.* ¶ 50.

B. LabCorp's Illegal Conduct and Relators' Claims

LabCorp is one of the largest nationwide providers of clinical laboratory services. FAC ¶ 59. As a key component of its business, LabCorp provided physicians' offices phlebotomy services either through: (1) IOPs in the offices of LabCorp's referring physicians, or (2) phlebotomy service centers ("PSCs") in close proximity to LabCorp's referring physicians. *Id.* ¶ 71. Here, LabCorp's provision of free phlebotomy services to LabCorp's physician customers ensured that HDL and Singulex continued receiving referrals. *Id.* ¶¶ 504–07. Without the blood samples drawn by LabCorp, HDL and Singulex would not have performed tests or submitted the

[2] At the stage of the proceedings, the Court must accept as true Relators' allegations regarding their personal observations of LabCorp's conduct.

related claims to government health care programs or private insurers in California or Illinois. *Id.* ¶ 261. LabCorp's IOPs also provided additional services beyond free blood draws, including handling much of the "processing," which was purportedly performed by LabCorp's physician clients in exchange for the HDL and Singulex kickbacks, amounting to millions of dollars in total. *Id.* ¶ 260. In exchange for providing these services, LabCorp's physician clients referred other clinical laboratory tests, including some that were medically unnecessary, to LabCorp. *See id.* ¶ 330.

LabCorp's illegal conduct resulted in submission of false claims in at least three ways. *First*, LabCorp caused the submission of false claims by drawing blood for HDL and Singulex. *Id.* ¶ 21. LabCorp knew by early 2010 that HDL and Singulex were paying improper kickbacks to physicians in exchange for referrals. *Id.* ¶ 262. However, LabCorp knowingly continued drawing blood tainted by these kickbacks. *Id.* ¶¶ 331–32. In exchange, LabCorp received referrals for LabCorp tests from the same physicians, received payments from HDL and Singulex, and sought strategic partnerships with HDL, Latonya Mallory, and Singulex. *Id.* ¶¶ 388, 445, 506. Accordingly, each claim submitted by HDL or Singulex for a patient whose blood was drawn by LabCorp was a false claim because each was tainted by an AKS violation. *Id.* ¶ 20.

Second, LabCorp violated the federal FCA by submitting its own false claims because it provided physicians with "in-kind" kickbacks in the form of free phlebotomy services and other "processing & handling" of blood samples, which were then sent to HDL or Singulex. *Id.* ¶¶ 377–78. Specifically, LabCorp provided processing and handling that the physicians were purported to perform in order to disguise the kickback scheme. *Id.* ¶¶ 502–03. Whether the phlebotomy and other services were provided by an IOP or PSC, LabCorp provided these services for no charge in exchange for direct referrals to LabCorp by the physicians. *Id.* ¶¶ 506, 508. Accordingly, each

claim submitted by LabCorp for its own testing related to a referral by a physician group that also was receiving HDL and Singulex kickbacks was a false claim. *Id.*

Third, LabCorp submitted its own false claims and caused the submission of false claims by HDL and Singulex by drawing the blood for, and submitting medically unnecessary tests that were duplicative of, tests simultaneously conducted by LabCorp on the one hand, and HDL or Singulex on the other hand. *Id.* ¶¶ 361–69. LabCorp knew when its own tests were medically unnecessary, but encouraged physicians to submit these tests by charging a draw fee or refusing to draw altogether when a physician failed to refer other tests to LabCorp. *Id.* ¶¶ 367–69. Accordingly, all claims submitted by LabCorp which were drawn by a LabCorp IOP or PSC that simultaneously drew blood for a duplicative test referred by the same physician to HDL or Singulex were false claims. *Id.* ¶¶ 361–69.

LabCorp's illegal conduct gives rise to Relators' four separate grounds of liability:

Count 1: 31 U.S.C. § 3729(a)(1)(A) – (C)	**Count II:** 31 U.S.C. § 3729(a)(1)(G)	**Count III:** California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871 et seq. ("CIFPA")	**Count IV:** Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92/1 et seq. ("ILCFPA")
Factual Basis: All three schemes of illegal conduct discussed above from early 2010 through 2014.	Factual Basis: LabCorp's claims paid by government programs prior to the submission of fraud alerts in 2013 and 2014.	Factual Basis: All three schemes of illegal conduct discussed above from early 2010 through 2014.	Factual Basis: All three schemes of illegal conduct discussed above from early 2010 through 2014.

LabCorp's Motion mischaracterizes LabCorp's conduct as "good-faith," "patient-minded," and "perfectly legal." Motion p. 1. LabCorp argues that a "company typically does not report a fraud to the government for which it would *itself* be liable." *Id.* (emphasis in original). However, the FAC provides ample allegations, taken as true for purposes of this Motion, to show LabCorp

simultaneously pursued two only *seemingly* inconsistent courses of conduct. On the one hand, LabCorp knew that HDL and Singulex were paying illegal kickbacks, knowingly drew and processed blood samples that were delivered to HDL and Singulex so they could effectuate their kickback scheme, and sought beneficial business relationships with both HDL and Singulex, ultimately leading to LabCorp's involvement in the conspiracy. *Id.* ¶¶ 68–69. On the other hand, LabCorp drafted and submitted a request for a fraud alert, which described HDL and Singulex as bad actors, yet neglected to disclose LabCorp's own fraudulent conduct. *Id.* ¶¶ 324–27. LabCorp fully recognized the critical role it played in keeping blood samples flowing to HDL and Singulex, that it was submitting false claims for medically unnecessary and duplicative testing, and that it was providing in-kind remuneration to physicians. *Id.* ¶¶ 361–69. Even as LabCorp developed a relationship with HDL and Singulex, LabCorp sought to remove the competition that HDL and Singulex posed and deflect attention from its own unlawful conduct by reporting its co-conspirators to the Government. *See id.* ¶¶ 324–27.

In fact, while LabCorp recognized in early 2010 that the HDL/Singulex scheme was a violation of the AKS, LabCorp actively and simultaneously pursued business relationships with both labs. *Id.* ¶¶ 379–446. LabCorp invoiced HDL for more than $7.6 million for tests it performed for HDL through July 2014, sought to purchase HDL, and continued developing a deeper relationship with HDL and its founder, Latonya Mallory. *Id.* ¶¶ 388–422. Likewise, LabCorp courted Singulex, even contracting to provide one of the tests in the Singulex panel, which was tied to physician kickbacks. *Id.* ¶ 436. In 2012 and 2013 alone, LabCorp more than $277,500 from Singulex for LabCorp testing services. *Id.* ¶ 445.

III. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v.*

Iqbal, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). A motion to dismiss under Rule 12(b)(6) "should not be granted unless it appears certain that the plaintiff can prove no set of facts which would support its claim and would entitle it to relief." *Mylan Labs., Inc. v. Matkari,* 7 F.3d 1130, 1134 (4th Cir. 1993). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal,* 556 U.S. at 668.

A complaint alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). However, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* To meet this standard, the complaint must describe "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370, 379 (4th Cir. 2008) (quoting *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776, 784 (4th Cir. 1999)). In other words, the complaint must describe the "who, what, when, where, and how of the alleged fraud." *Id.* (quoting *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.,* 336 F.3d 375, 384 (5th Cir. 2003) (internal quotation marks omitted)). Finally, "[a] court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial pre-discovery evidence of those facts." *Harrison,* 176 F.3d at 784. Rule 9(b) also requires a complaint to include "some indicia of reliability" to "support the allegation that an actual false claim was presented to the government." *Nathan,* 707 F.3d at 457 (internal citation omitted). A complaint provides the requisite indicia of reliability where "specific allegations of the defendant's fraudulent conduct necessarily [lead] to the plausible inference that false claims were

presented to the government." *Id.*

IV. ARGUMENT

Taking the facts alleged in the FAC as true, together with the reasonable inferences from those facts, Relators have alleged more than sufficient facts to support LabCorp's unlawful conduct as alleged in all four Counts of the FAC. Specifically, LabCorp's motion to dismiss fails because: (1) LabCorp encouraged physicians to submit medically unnecessary testing to LabCorp, HDL, and Singulex, thereby submitting its own false claims and causing the submission of false HDL and Singulex claims; (2) in the alternative, LabCorp is liable for reverse false claims by virtue of LabCorp's separate efforts to conceal its obligations through misleading requests for fraud alerts; (3) Relators are "interested persons" within the meaning of California and Illinois's private insurance *qui tam* statutes and have alleged LabCorp's nationwide fraudulent scheme with particularity; and (4) LabCorp played an essential role the conspiracy to submit fraudulent HDL and Singulex claims.

A. LabCorp Improperly Encouraged Medically Unneccesary Testing, Thereby Submitting and Causing the Submission of False Claims

LabCorp argues that it played "no role" in determining which tests were submitted by referring physicians, and that LabCorp never certified the medical necessity of a physician's tests. Motion pp. 9–10. LabCorp incorrectly concludes that it cannot be liable for knowingly submitting or causing the submission of medically unnecessary claims to government programs or private insurers. *See id.* p. 9 (noting that "Relators' third theory . . . spans all four counts"). In short, LabCorp argues that (taking Relators' allegations as true) even though the company knew the claims were medically unnecessary and induced by LabCorp's actions, it cannot be liable for the related false claims because a physician (not LabCorp) ordered the tests. *See* FAC ¶¶ 330–37.

Medicare, Medicare Advantage plans, Medicaid, and TRICARE only cover those services,

including laboratory testing, that are medically necessary. *See id.* ¶¶ 116, 120–21, 130, 145, 153; *see, also* Social Security Act § 1862(a)(1)(A) (codified at 42 U.S.C. § 1395y(a)(1)(A)); South Carolina Health and Human Services Physicians Provider Manual, Section 2, p. 2-186 ("All laboratory tests are subject to medical necessity guidelines[.]").[3] Likewise, both CIFPA and ILCFPA prohibit fraudulent claims to private insurers. Private insurance plans mirror Government program requirements, including the requirement that "laboratory testing is billed to private insurers is not the result of an illegal inducement, and is medically necessary." FAC ¶ 155; *see also* Cal. Ins. Code § 1871.7; 740 Ill. Comp. Stat. § 92/1.

LabCorp's argument here fails because clinical laboratories are liable for medically unnecessary tests ordered by physicians when the laboratory causes the submission of the unnecessary claims. The two cases cited by LabCorp to support its contrary proposition actually support the legal sufficiency of Relator's lack-of-medical-necessity claims. *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 159 (D.D.C. 2017); *United States v. Bertram*, 900 F.3d 743 (6th Cir. 2018).[4]

A clinical laboratory "*certifies* that the tests performed were medically necessary." *Groat,* 296 F. Supp. 3d at 159 (quoting *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 25 (D.D.C. 2017)) (emphasis in original). Typically, a clinical laboratory "is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary."

[3] Available at https://www.scdhhs.gov/internet/pdf/manuals/Physicians/Section%202.pdf

[4] In *Bertram*, the U.S. Court of Appeals for the Sixth Circuit held that a "laboratory generally may rely on [a] doctor's order in submitting a claim for reimbursement as medically necessary." *Bertram*, 900 F.3d at 750. However, the court concluded that when the laboratory's conduct caused the test to become medically unnecessary by waiting for several months to run the test, the laboratory could no longer rely on the physician's earlier assessment of medical necessity to file a claim. *Id.*

Id. However, a clinical laboratory still "has a role to play to ensure that it does not submit claims for medically unnecessary tests." *Id.* (citing Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45077 (Aug. 24, 1998)).

Accordingly, a relator adequately alleges that false claims were submitted by a clinical laboratory if he contends that the laboratory's conduct caused the submission of medically unnecessary tests. *Id.* at 165; *see also Bertram*, 900 F.3d at 750. For instance, in *Groat*, the relator adequately alleged a violation of Medicare regulations because the relator alleged a scheme by Boston Heart to "encourage . . . physicians to order medically unnecessary tests through a false marketing campaign and pre-printed test requisition forms[.]" These allegations were sufficient to demonstrate that Boston Heart committed a "knowing violation of [the laboratory's] 'legal duty to ensure that it is not submitting false or incorrect claims to Government . . . payors[.]'" *Id.* (quoting OIG Guidance, 63 Fed. Reg. at 45,077 and 45,079–080).

Consistent with these principles, this Court has denied a motion to dismiss in the related case, *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498–99 (D.S.C. 2016), that raised the same arguments. There, the Court held that allegations of claims submitted for medically unnecessary services and identification of one physician who was encouraged to order panels of medically unnecessary tests for patients was sufficient to survive a motion to dismiss. *Id.*

Similarly, in *United States ex rel. Downy v. Corning, Inc.*, the relator alleged that a laboratory company encouraged medically unnecessary testing by combining two distinct tests into a single line, such that the physician could not order a medically necessary test without ordering the second test that might not have been medically necessary. 118 F. Supp. 2d 1160, 1172 (D.N.M. 2000). The court noted that this allegation, along with a copy of the test order form,

sufficiently alleged the "general mechanics of the scheme." *Id.* at 1173. Accordingly, the court declined to dismiss the complaint. *Id.*

Here, Relator alleges that LabCorp submitted or caused the submission of medically unnecessary tests in two ways: (1) by encouraging physicians to continue referring medically unnecessary testing to HDL and Singulex; and (2) by encouraging physicians to submit medically unnecessary tests to LabCorp in exchange for LabCorp's provision of phlebotomy services related to the HDL and Singulex kickback scheme.

(i) LabCorp caused submission of false claims by knowingly encouraging physicians to refer medically unnecessary testing to HDL and Singulex

LabCorp facilitated physicians' referrals of medically unnecessary testing by providing a critical component of the submission of HDL and Singulex claims: "Since at least the spring of 2010, LabCorp knew that HDL and Singulex were providing illegal inducements in the form of above-market [fees] to referring physicians and physician practices." FAC ¶ 262. LabCorp "acknowledged that [it] should not be providing free blood draw and /or processing services for blood samples referred to HDL and Singulex by physicians in exchange for above-market [fees]." *Id.* ¶ 264. Yet LabCorp provided blood draws and processing services from 2010 through at least June 2014. *Id.* ¶ 331. As part of the scheme, "physicians received and accepted offers of remuneration to refer patients to HDL, Singulex, and LabCorp for testing, even where testing was not medically necessary." *Id.* ¶ 529; *see, also id.* at ¶¶ 535–36.

As a reflection of the critical role of phlebotomy services in the HDL and Singulex scheme, the new customer forms for both HDL and Singulex "contained information regarding whether blood draws were performed in the doctor's office." *Id.* ¶ 502. This was "critical to HDL and Singulex because these tests were marketed as a revenue stream for the referring physician." *Id.* ¶ 503. To profit from the medically unnecessary tests submitted to HDL and Singulex, a physician

"either had to employ a lab technician or obtain the services of a technician from an independent lab" such as LabCorp. *Id.* ¶¶ 504–05. Accordingly, LabCorp "facilitate[d] the fraud by HDL and Singulex" by "provid[ing] referring physicians, including Dr. Miller, with free blood draw and processing services." *Id.* ¶ 507. Just as in *Groat*, *Downy*, the previously decided case against HDL and BlueWave and its principles, LabCorp's provision of IOPs encouraged and enabled the submission of medically unnecessary tests to HDL and Singulex. *Groat*, 296 F. Supp. 3d at 165; *Downy*, 118 F. Supp. 2d at 1172–73; *Berkeley*, 225 F. Supp. 3d at 498–99.

(ii) LabCorp knowingly encouraged referrals of medically unnecessary testing to LabCorp

In addition to the critical role that LabCorp played in causing the submission of medically unnecessary tests by HDL and Singulex, LabCorp separately encouraged referrals by physicians to enrich itself through a policy designed to ensure that each HDL or Singulex blood draw included a lab test referral to LabCorp, whether or not the LabCorp test was medically necessary.

For example, Relators allege that in September 2012, LabCorp salesman Jason Erxleben "made it clear [to Dr. Miller] that LabCorp was willing to continue to provide Dr. Miller with free blood draw and processing services for referrals to HDL and Singulex as long as Defendant LabCorp also received referrals for lipid testing." FAC ¶ 353. In the absence of a referral to LabCorp, "LabCorp wanted to charge Dr. Miller a $5.00 fee per patient." *Id.* When obtaining LabCorp's phlebotomy services, "Dr. Miller wrote all of the clinical laboratory tests for his patients on the LabCorp requisition form." *Id.* ¶ 365. The LabCorp requisition includes a space marked "other" where Dr. Miller or his staff hand wrote "HDL/Singulex." *Id.* To keep the money flowing, "Dr. Miller regularly referred patients to LabCorp for tests that were in part duplicative of the testing services he referred to HDL." *Id.* ¶ 361. "[O]n November 6, 2012, Dr. Miller referred patient B.B. to HDL for, among other things, a lipid-panel test[.]" Dr. Miller also referred B.B. to

LabCorp for the same tests on the same day." *Id.* These referrals to "HDL and LabCorp for duplicative tests" became Dr. Miller's "standard practice." *Id.* In fact, similarly duplicative tests were submitted for patients DDF, EAD, and LB in May 2011, August 2011, and December 2012, respectively. *Id.* ¶ 362.

LabCorp "knew when tests ordered by Dr. Miller selected on the LabCorp requisition were duplicative of tests referred to HDL because the LabCorp requisition clearly shows both HDL and Singulex referrals, plus a number of referrals for LabCorp testing." *Id.* ¶ 366. LabCorp's "technician drew blood for all of the laboratory testing, including HDL, Singulex, and LabCorp." *Id.* ¶ 367. "Based on the technical knowledge and experience required for LabCorp phlebotomists, the LabCorp employee knew or should have known when tests referred to LabCorp by Dr. Miller were duplicative of tests referred to HDL." *Id.*

In sum, like the relators in *Groat* and *Downy*, Relators have alleged a scheme by which LabCorp encouraged the submission of medically unnecessary tests. *Groat*, 296 F. Supp. 3d at 165; *Downy*, 118 F. Supp. 2d at 1172–73. The facts described above demonstrate LabCorp's "knowing violation of [the laboratory's] 'legal duty to ensure that it is not submitting false or incorrect claims to Government . . . payors[.]'" *Groat*, 296 F. Supp. 3d at 165.

B. LabCorp is Liable for Reverse False Claims

(i) LabCorp's conduct in submitting reverse false claims provides an alternative ground for liability

LabCorp argues that Relators have not adequately alleged reverse false claims because the allegations in Count II are redundant of Counts I, III, and IV. However, it is proper to plead claims in the alternative. Fed. R. Civ. P. 8(d)(2). Relators allege that LabCorp is liable for reverse false claims in the alternative to the other false claims because LabCorp engaged in separate conduct related to this claim in order to conceal its responsibility to return improper payments. Under 31

U.S.C. § 3729(a)(1)(G), any person who "knowingly conceals . . . an obligation to pay or transmit money or property to Government" is liable. *See United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1229 (11th Cir. 2012) (reversing district court's dismissal of reverse false claims where complaint alleged a contractual obligation to return property, the identification of the obligation by the defendant, and a false record submitted to conceal the obligation).

Here, Relators allege that LabCorp received improper payments from claims it submitted that were tainted by AKS violations through the provision of free phlebotomy and other services to physicians. FAC ¶ 572. LabCorp was required to return these payments under the PPACA's amendments to the AKS. *See id.* ¶¶ 167–68; 590. Under the PPACA amendments, the Social Security Act requires any person who receives an overpayment to report and return the overpayment within 60 days of identifying it. *See* 42 U.S.C. § 1320a-7k(d). Failure to report and return an overpayment is actionable as a violation of 31 U.S.C. § 3729(a)(1)(G). *See* 31 U.S.C. § 3729(b)(3) (defining "obligation" as "an established duty, whether or not fixed, arising from . . . the retention of any overpayment.").

LabCorp engaged in distinct conduct intended to deprive Government healthcare programs and private insurers of the ability to uncover its fraud. FAC ¶ 581. For example, LabCorp submitted requests for OIG fraud alerts (while actively pursuing and engaging in business with HDL and Singulex) through which LabCorp concealed its own participation in the fraudulent scheme. *Id.*; *see also id.* ¶¶ 324–27, 382, 392, 420. LabCorp's conduct occurred in the confines of the physician's office or a LabCorp PSC. *Id.* ¶ 581. The Government did not know which HDL, Singulex, and LabCorp tests were being ordered, drawn, and processed for the patient referrals that were impacted by the LabCorp, HDL, and Singulex inducements. *Id.*; *see also id.* ¶¶ 437–38. In other words, LabCorp's fraudulent conduct in drafting and submitting the requests for

fraud alerts—while simultaneously participating in the fraud—was an overt act to conceal its obligation to report and return the payments it received up to that point as a result of its own kickbacks. *Id.* ¶ 581.

As noted above, Counts I,[5] III, and IV are based on allegations LabCorp: (1) caused HDL and Singulex's submission of false claims by encouraging medically unnecessary laboratory testing; (2) submitted its own false claims by encouraging physicians to refer patients for medically unnecessary testing; and (3) conspired with HDL and Singulex to submit false claims. These wrongful acts occurred between early 2010 through 2014, with the exception of the conspiracy which began by at least late 2010. In contrast, Count II is based on LabCorp's direct claims submitted *prior to* the fraud alerts. Thus, while there is some overlap between the factual basis for each Count, Count II liability may exist even where liability under Counts I, III, and IV does not. It is appropriate to assert these claims in the alternative as Relators have done here. Therefore, the Court should deny LabCorp's motion regarding Count II at this stage of the proceedings.

(ii) Relators' reverse false claims allegations satisfy Rule 9(b) requirements

LabCorp contends that Relators' Count II claim should be dismissed because it fails to allege the "time, place, or substance of any retained overpayments" from the federal government. Motion p. 15. The FAC, however, provides detailed allegations regarding LabCorp's efforts to conceal its obligation to return overpayments through fraud alerts. FAC ¶¶ 324–27.

To adequately plead a reverse false claim under Rule 9(b) a relator must identify: (1) an obligation to pay funds to the government; (2) the parameters of the obligation; and (3) an action to conceal or diminish that that obligation. *United States ex rel. Branscome v. Blue Ridge Home*

[5] As stated above, LabCorp has not sought dismissal of the kickback allegations in Count I and has limited its Motion to the medical necessity allegations.

Health Servs., Inc., 2018 WL 1309734, at *5 (W.D. Va. Mar. 13, 2018) (citing *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 88 (D.D.C. 2014).[6]

First, LabCorp had an obligation to return funds that it received as an overpayment under federal statutes, including the PPACA. FAC ¶ 168 (discussing 31 U.S.C. § 3730(a)(1)(G) and Social Security Act Section 1128J(a) (codified at 42 U.S.C. 1320a-7k)). Under the Social Security Act, LabCorp is required to return any overpayment that it receives from a federal healthcare program within 60 days of identifying the overpayment. 42 U.S.C. 1320a-7k(d)(2)(A). Here, Relators allege that LabCorp was aware that it was receiving funds from Medicare from the claims it had submitted—and knew the claims for those funds were tainted by kickbacks as early as spring of 2011. FAC ¶ 262. Relators further allege that LabCorp was aware that "it should not be providing free blood draw and/or processing services for blood samples referred to HDL and Singulex by physicians in exchange for above-market draw fees or P&H fees." *Id.* ¶ 264. However, LabCorp continued drawing for HDL and Singulex, so long as it received a referral from the physician. *Id.* ¶ 332. LabCorp then submitted these claims "multiple times per year for many beneficiaries of Medicare and other Government healthcare programs." *Id.* ¶ 558; *see also id.* Ex. D (listing sample claims submitted directly by LabCorp). Therefore, LabCorp's obligation to return the overpayments for these claims arose no later than 60 days after spring of 2011. *Spires v. Schools*, 271 F. Supp. 3d 795, 800 (D.S.C. 2017) ("A complaint has 'facial plausibility' where the pleading 'allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'") (quoting *Iqbal*, 556 at 678).

[6] If the claim is based on defendant's action in making, using, or causing to be made a "false record or statement," such statement must be "material to [the] obligation to pay or transmit money or property to the Government[.]" 31 U.S.C. § 3729(a)(1)(G). This materiality requirement does not apply where, as here, the defendant "knowingly conceals" its obligation.

Second, Relators allege that the parameters of LabCorp's obligation can be measured by the leakage reports that LabCorp both obtained from insurers and developed internally. At least since 2010, LabCorp "received so-called 'Leakage Reports' from insurers, including . . . managed care plans, including Medicare Part C plans and Medicaid managed care plans." FAC ¶ 278. These leakage reports "are detailed lists of specific patient referrals by physicians to laboratory providers that were 'out-of-network,'" including HDL and Singulex. *Id.* ¶ 279. Relators further allege that LabCorp then used the leakage reports to track "customers' compliance with using in-network labs; and [] monitor which customers were referring patients to competitor labs for tests that could be performed by LabCorp." *Id.* ¶ 281. LabCorp further developed internal leakage reports. *Id.* ¶ 292. These internal leakage reports included "a wealth of data for each referring physician who was sending tests to LabCorp's competitors[,]" including HDL and Singulex. *Id.* Furthermore, LabCorp developed specialized leakage reports that "detailed LabCorp physician customers who were leakers who 'overlapped,' by appearing on more than one insurer's Leakage Reports." *Id.* ¶ 310. Accordingly, LabCorp could readily identify the physicians for which it drew blood and submitted its own claims during the time period the physician customer was also receiving kickbacks from HDL and Singulex. *Spires*, 271 F. Supp. 3d at 800 (allowing reasonable inference). LabCorp's claims on these accounts resulted in the overpayments at issue in Count II. *Id.*

Finally, Relators allege that LabCorp engaged in separate conduct to conceal its obligation to return these overpayments through the drafting and submission of misleading requests for OIG fraud alerts. FAC ¶¶ 324–27. LabCorp developed its initial request for fraud alert starting in April 2012. *Id.* ¶ 324. However, the 2012 deadline to submit a request for fraud alerts had passed, so "[i]n early 2013, LabCorp submitted its first request for a fraud alert." *Id.* ¶ 325. The following

year, "LabCorp submitted a second request for a fraud alert against HDL and Singulex." *Id.* ¶ 326. These fraud alerts disclosed HDL and Singulex kickback fraud, "described the two companies as 'bad actors' and identified their bogus 'draw fees' and 'P&H' fees as fraud[.]" *Id.* ¶ 327. LabCorp further "referred to HDL and Singulex offering physicians 'inflated payments for collecting and processing specimens' despite 'clear OIG warnings since at least 2005.'" *Id.* However, LabCorp "deprived Government healthcare programs of the ability to uncover [LabCorp's] fraud." *Id.* ¶ 581. Instead, "LabCorp concealed from the government by omission its own fraudulent participation in the conduct which resulted in false LabCorp . . . claims." *Id.* In short, LabCorp's requests for fraud alerts "knowingly conceal[ed] . . . an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

In sum, the FAC adequately states a claim under Rule 9(b) for reverse false claims.

C. Relators Have Standing to Bring Claims Under California and Illinois Qui Tam Statutes and These Claims Meet Rule 9(b) Particularity Requirements

LabCorp argues *first*, that Relators lack standing to bring claims under CIFPA and ILCFPA, and *second*, that their claims under both statutes are subject to dismissal for failure to state a claim. Neither of these arguments is persuasive.

(i) Relators have standing as "Interested Persons" under CIFPA and ILCFPA

LabCorp first makes the novel argument that Relators Lutz and Webster lack standing to sue under CIFPA and ILCFPA because they are not "interested persons" under the statutes. No case law supports LabCorp's proposition. Specifically, *State ex rel. Zolna-Pitts v. ATI Holdings*, Inc., No. 12CH27483, 2013 WL 3779568 (Ill. Cir. Cit. Jun. 18, 2013), does not, as LabCorp contends, interpret "interested persons" to "require that the alleged fraud have 'affected or involved' the relator." Motion p. 17 (quoting *Zolna-Pitts*, 2013 WL 3779658, at *2). In that unpublished decision, the trial-level court found that the relator, who had worked for the defendant,

qualified as an "interested person" under ILCFPA. However, it did not hold that relators who were not connected to the defendant through employment or otherwise would not have standing to sue.

Significantly, *Zolna-Pitts* relies on a California case, *People ex rel. Strathmann v. Acacia Research Corp.*, 2010 Cal. App. 4th 487 (Cal. Ct. App. 2012)—a case that LabCorp neglects to cite. There, the California Court of Appeal held that another former-relator employee was an "interested person" under CIFPA, but it made clear that the relator's standing *did not* depend on his employment status. Rather, Strathmann was "an 'interested person' by virtue of his status as a *qui tam* relator. 'A *qui tam* relator is essentially a self-appointed private attorney general, and his recovery is analogous to a lawyer's contingent fee.'" *Id.* at 500-01. Strathmann's status as a relator supported the court's conclusion that he was an "interested person" under the California statute.

Such an interpretation is consistent with the purpose of enacting *qui tam* provisions in fraud statutes, such as CIFPA and ILCFPA, which allow plaintiffs with information about fraudulent conduct to sue on behalf of the government entities (and in this case, state insurance departments). Thus, assessing relators' standing based solely on their relationship with defendants—or even the states themselves—would be nonsensical. In every *qui tam* action, the relator has no personal right to recover the damages sought, and the government entities are the real parties in interest. *E.g., United States ex rel. Milam v. University of Texas M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992). Even a competitor to a defendant may bring an action as a relator.[7] Accordingly,

[7] *See, e.g.,* Press Release, *available at:* https://www.justice.gov/usao-edpa/pr/settlement-announced-whistleblower-suit-against-shredding-companies (in *United States ex rel. Douglas Knisely v. Iron Mountain Inc. et al.*, competitors (the quintessential "outsiders") made effective relators because they assist the government by leveling the playing field to remove corrupt practices that provide competitive advantage to fraudsters); *see also* http://vaquitamlaw.com/use-of-the-qui-tam-provisions-of-the-federal-false-claims-act-by-business-owners-to-level-the-playing-field/.

standing to bring an action under any *qui tam* statute is conferred on relators not because of an alleged personal injury—and not, as the motion implies, because of the relators' connection to the defendants or the states—but because of the concrete and actual harm suffered by the government entity as a result of fraud. *E.g.*, *Vt. Agency of Nat'l Resources v. United States ex rel. Stevens*, 529 U.S. 765, 773-74 (2000).

Notably, the California Department of Insurance ("CDI"), which is charged with investigating potential violations under CIFPA and is actively investigating Relators' allegations against LabCorp, agrees with Relators' interpretation of the statute. CDI has submitted a statement of interest, which is attached to this Response as Exhibit 1. Therein, CDI explains that, under California case law and a common-sense interpretation of CIFPA, Relators need not suffer their own injuries to be considered "interested persons," because the statute is intended to vindicate injuries suffered by private healthcare insurers. Indeed, a potential relator qualifies as an interested person under CIFPA as long as he or she is the original source of the information, and the lawsuit is not based on allegations previously disclosed in another proceeding or by the media. Exhibit 1 at 6–7.

Even if there were some question as to whether Relators were "interested persons" under CIFPA – and there is not – the Court should decline to dismiss Relators' claims at this juncture as the CDI is still investigating the Relators' allegations against LabCorp. *Id.* at 1–2. Should the CDI intervene in the lawsuit, it would take over the primary responsibility for prosecuting Relators' claims, and Relators' standing would thus be irrelevant.

(ii) Relators have met the pleading requirements of Rule 9(b) with respect to their California and Illinois claims by alleging a nationwide fraudulent scheme that includes specific conduct occurring in each state.

LabCorp also contends that Relators have not alleged their CIFPA and ILCFPA claims with adequate specificity because they failed to identify: (1) false claims submitted by LabCorp to

a California or Illinois insurer, and (2) private insurance policies that were breached by the unlawful conduct. Motion, at 17-18. In doing so, LabCorp has repackaged the argument that former HDL CEO Latonya Mallory made in her failed effort to dismiss Relator's CIFPA and ILCFPA claims in the severed case against BlueWave and the individuals who led HDL and BlueWave (Mallory, Dent, and Johnson). *See Berkeley*, 225 F. Supp. 3d at 508–09. This Court rejected the argument then, and it should reject it now.[8] *Id.*

Contrary to LabCorp's assertion, Relators need not identify specific claims submitted to California or Illinois insurers. Instead, Relators can satisfy Rule 9(b) by alleging "specific claims in one state or region," coupled with facts establishing an inference of nationwide fraud. *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 174-75 (E.D. Pa. 2012) (collecting cases); *see also Berkeley*, 225 F. Supp. 3d at 508–09 *United States ex rel. Drennen v. Fresenius Med. Care Holdings, Inc.*, 2012 WL 8667597, at *1-2 (D. Mass. Mar. 6, 2012); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of America*, 238 F. Supp. 2d 258, 268 (D.D.C. 2002).

Here, Relators have identified both specific conduct in support of their allegations that LabCorp submitted its own kickback-tainted claims and also caused the submission of kickback-tainted claims by HDL and Singulex arising from Relators' knowledge of the conduct in South Carolina. FAC Exs. A–D. Relators have alleged and provided examples of claims submitted to government healthcare programs as well as private insurers. They have also provided sweeping

[8] LabCorp's argument that the Court granted summary judgment against Relators' CIFPA and ILCFPA claims in the Bluewave litigation is irrelevant. The reason those claims were dismissed—after months of fact discovery—is that Relators were unable to secure claims data at that time from the state insurance departments. Relators are not required to obtain such data at the motion to dismiss stage, and LabCorp does not (and cannot) argue to the contrary.

and detailed allegations in support of their nationwide allegations, including facts suggesting that the fraud occurred in California and Illinois. These allegations include, but are not limited to:

- LabCorp monitored the involvement of physicians throughout the country who were referring tests to HDL and Singulex. FAC ¶¶ 314-23. These ad-hoc reports were generated from a number of states including California, Alabama, Colorado, North Carolina, South Carolina, and Washington.

- Since before June 2010, LabCorp received "leakage reports," which were detailed lists of patients covered by both government healthcare programs and private insurers who were referred by LabCorp's physician customers to out-of-network laboratories (like HDL and Singulex), including public and private payors based in California and Illinois. *Id.* ¶¶ 278-313. The beneficiaries identified in those reports included individuals who lived in both Illinois and California. For example, Plaintiffs alleged that the Leakage Reports revealed that one Santa Clara, California-based physician LabCorp customer referred 157 patients per month to HDL between October and December 2013. *Id.* ¶ 298.

- LabCorp created its own internal leakage reports, which included customers from every region in the country, including California specifically. *Id.* ¶¶ 297-98.

- LabCorp does business with commercial insurers in California (including but not limited to Aetna, Blue Cross Blue Shield, Cigna, Humana, Kaiser Permanente, and UHC) and Illinois (including but not limited to Aetna, Blue Cross Blue Shield, Cigna, and Humana). *Id.* ¶ 80. These same insurers paid for tests performed by HDL and Singulex. *Id.* ¶¶ 93, 101. Specific examples of Blue Cross Blue Shield patients referred to HDL and Singulex are provided in Exhibits B and C to the Complaint. *Id.* ¶ 536.

- BlueWave, through Dent and Johnson, and HDL promoted HDL products throughout the country, including specifically in California. *Id.* ¶¶ 468-71.

- HDL derived substantial revenue from private insurers, including those in California and Illinois. *Id.* ¶ 85.

- From at least late 2010, LabCorp knew, from leakage reports and ad hoc reports, of the national scheme to promote HDL and Singulex testing through the payment of inducements to LabCorp physician customers. Relators alleged that specific LabCorp employees with jurisdiction over and/or who worked in California, continued to add to LabCorp's organizational knowledge of the scheme. *Id.* ¶ 323.

Relators have not only alleged a nationwide fraudulent scheme involving LabCorp, but they have also alleged specific connections between the scheme and both California and Illinois.

They have thus put LabCorp "on notice of the who, what, when, where, and how of the fraud." *Berkeley*, 225 F. Supp. 3d at 509. The FAC thus satisfies Rule 9(b)'s pleading requirements.

Next, LabCorp contends that Relators have failed to plead CIFPA and IFCPA violations with particularity because they have not identified the private insurance policies that were breached. Motion pp. 21–23. This argument fails. As Relators pleaded in the FAC, submitting kickback-tainted claims to insurers in California and Illinois is a *per se* violation of CIFPA and IFCPA, respectively. FAC ¶¶ 179, 181. Whether the insurance policies expressly recognize the illegality of kickbacks does not make the kickbacks more or less unlawful.

United States v. Triple Canopy, Inc., 775 F.3d 628 (4th Cir. 2015), on which LabCorp relies, is not to the contrary. There, a relator alleged that a contractor had defrauded the government by breaching five different contracts requiring that guards at five separate military bases in Iraq have a certain level of training. *Id.* at 640. The complaint contained specifics as to one contract, but, as to the others, argued only that the contractors were transferred to different bases while still unqualified to provide security services. *Id.* The U.S. Court of Appeals for the Fourth Circuit held that the complaint did not satisfy Rule 9(b) as to claims arising under four of the contracts because the relator had merely presumed the submission of claims that were false under the contracts' terms.[9] *Id.*

Far from alleging that LabCorp has violated the CIFPA and IFPCA because it was defrauding governmental health care programs based on conduct occurring in South Carolina,

[9] *Takeda* and *Siemens* do not rescue LabCorp from its wrongful conduct. *U.S. ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 515 (E.D. Pa. 2010); *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456–57 (4th Cir. 2013). In *Siemens*, the facts alleged were similarly focused on four contracts out of a total of 21. *Siemens*, 708 F. Supp. 2d at 515. In *Takeda*, the relator did not allege a nationwide scheme and failed to identify any claims that were actually submitted as part of the scheme. *See Takeda*, 707 F.3d at 454–55.

Relators have made specific allegations that the fraud was nationwide, including in California and Illinois. LabCorp argues that the state law claims are defective, in part, because one paragraph alleges the nationwide scheme on "information and belief." Motion p. 21. However, this argument ignores the specific allegations detailing the nationwide scheme. In particular, Relators have alleged that: (1) LabCorp does business with specific insurers in both California and Illinois, (FAC ¶ 80); (2) those same insurers paid for tests performed by HDL and Singulex, (*id.* ¶¶ 93, 101); (3) many, if not all, of the tests that HDL and Singulex did were tainted by kickbacks in the form of illicit process and handling fees, (*e.g.*, *id.* ¶¶ 184–89); and (4) LabCorp (a) caused the presentment of claims for these tests in violation of CIFPA and IFCPA, including drawing and processing blood samples sent to HDL and/or Singulex (the triggering event for the kickback payment to referring physicians, including LabCorp's physician customers) and (b) made false statements to induce the payment of the tests in violation of the statutes. *Id.* ¶¶ 600–01, 611–12. These allegations give LabCorp more than sufficient notice of the claims against it.

Interestingly, LabCorp has not challenged Relators' standing to bring their *qui tam* action to recover for the national fraud involving referrals of government healthcare program beneficiaries, including those in California. Instead, LabCorp alleges only that the Relators' allegations are somehow insufficient as to beneficiaries covered by private insurance. It is illogical to concede that Relators have sufficient interest in pursuing federal FCA claims involving California providers' referrals of government healthcare program beneficiaries, but somehow lack a sufficient connection to the same providers' referrals of beneficiaries covered by private insurance.

D. LabCorp's Conspiracy Is Detailed with Sufficient Particularity in the FAC

LabCorp argues that Relators' conspiracy claim must be dismissed because the FAC: (1) fails to allege the existence of an unlawful agreement between HDL, Singulex, and LabCorp; (2)

fails to allege that HDL, Singulex, and LabCorp shared an intent to defraud the Government; and (3) LabCorp's request for fraud alerts undermines the conspiracy claim. As described below, the FAC provides detailed allegations that LabCorp entered an agreement with HDL, its founder Mallory, and Singulex, detailed allegations of LabCorp's shared intent to defraud the Government, and that LabCorp's "report" of the HDL and Singulex fraudulent practices was actually LabCorp's effort to conceal its own involvement in the scheme.

The conspiracy as alleged here involved LabCorp's active participation. HDL and/or Singulex obtained doctors' referrals through a marketing scheme based entirely on kickbacks. FAC ¶ 194. However, HDL and Singulex did not provide physicians with phlebotomists to extract the blood needed to consummate the referral, so LabCorp provided the blood draws and processing services through its IOPs and PSCs. *Id.* ¶ 103. LabCorp would draw and process the sample for the referral to HDL/Singulex, *id.* ¶ 311, which would run the test and submit the kickback-tainted claim, *id.* ¶ 497. LabCorp did not merely observe HDL and Singulex committing fraud, *id.* ¶¶ 278–323; it provided the essential services required for the kickback scheme. *See id.* ¶ 226 ("LabCorp provided all of the blood draw services, and virtually all of the processing services for tests on patients referred by Dr. Miller to Singulex."). But for LabCorp's blood draw, Singulex and HDL could not receive referrals, conceal their inflated fee payments as "processing and handling fees," or submit the false claim for payment. *Id.* ¶¶ 397 (HDL and LabCorp discussed the "mutually beneficial" use of LabCorp's phlebotomists).

LabCorp profited from this conspiracy in two ways. First, LabCorp established a policy by which it would only draw blood for tainted HDL or Singulex referrals when it received a referral to LabCorp from the physician. FAC ¶¶ 332, 337, 353. Second, LabCorp received direct payments from HDL and Singulex. *Id.* ¶¶ 388, 445. Once LabCorp provided the blood sample for Singulex

testing, it would perform some of the tests in the tainted Singulex and would be compensated for those tests. *Id.* ¶ 445. LabCorp also developed favorable business relationships with HDL worth millions of dollars. *Id.* ¶ 388.

(i) LabCorp's conduct evidences an unlawful agreement with HDL and Singulex

Relators have alleged ample facts to demonstrate an unlawful agreement between HDL, Singulex, and LabCorp. As this Court noted in *Berkeley*, the FAC "must alleged the existence of an agreement to violate the FCA and at least one act performed in furtherance of that agreement." 225 F. Supp. 3d at 501, 512; *see also United States ex rel. Ahumada v. NISH*, 756 F.3d 268, 282 (4th Cir. 2014) (noting that allegations of agreement must identify who was involved in the agreement, when the agreement was entered, and what the defendant sought to gain). In *Berkeley*, this Court held that the Government adequately stated a conspiracy claim by alleging that defendant Berkeley began paying kickbacks to physicians. *Id.* at 496. The parties then reduced their conspiracy to writing with a sales agreement that this Court described as a "supercharged version of the P&H Kickback Scheme" between HDL, BlueWave, Mallory, Dent, and Johnson. *Id.* at 497–98. Thus, the written agreement was not a necessary allegation, but an enhanced version of the scheme.

This is consistent with conspiracy allegations in other contexts. A conspiratorial agreement may be inferred from a course of conduct between the co-conspirators. "Allegations of communications and meetings among conspirators can support an inference of agreement because they provide the means and opportunity to conspire." *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 432 (4th Cir. 2015) (addressing conspiracy claim in context of the Sherman Act).

An agreement may also be inferred where the defendant continues to participate in an unlawful scheme after learning of its existence. For example, in *United States ex rel. DeCesare v. Americare In Home Nursing (DeCesare II)*, the court found that a complaint sufficiently stated a

claim for conspiracy. 2011 WL 607390 at *7 (E.D. Va. Feb. 10, 2011).[10] There, in an amended complaint, the relator alleged that defendants' representatives received a letter that identified violations of the AKS in a referral network. *Id.* at *4. The court noted that it had previously dismissed the claim for conspiracy against defendant MedStar because relator "presented no evidence of MedStar's awareness of an unlawful agreement nor any shared intent to defraud the government." *Id.* at *7. However, the amended complaint contained the allegation that "MedStar [knew], as of the first letter, that it may be participating in an illegal referral network, such that its continuing to do so afterwards constituted its assent to the other parties' allegedly illegal agreement." *Id.* Therefore, the court denied MedStar's motion to dismiss the conspiracy claim.

Here, by no later than June 2010, "LabCorp was aware that HDL was inducing its physician customers with $20 'draw fees'" and therefore "knew it should not be providing phlebotomy services for HDL [or Singulex] referrals." FAC ¶ 386; 426 (alleging LabCorp's knowledge of Singulex kickbacks). However, "[i]n spite of the company's knowledge of HDL's practice of paying referring physicians kickbacks," since at least the end of 2010, LabCorp continued to provide phlebotomy services for referrals to both companies and also pursued business relationships with HDL and Singulex. *Id.* ¶¶ 18, 388. LabCorp continued drawing blood for Singulex "through 2011, 2012, 2013, and 2014." *Id.* ¶ 430. LabCop also "focused on the EMV [or estimated monthly value] to LabCorp of the physician account," as a reason to participate in the HDL and Singulex fraud. *Id.* ¶ 432.

[10] LabCorp's Motion cites *United States ex rel. DeCesare v. Americare In Home Nursing* (*DeCesare I*), 757 F. Supp. 2d 573, 584 (E.D. Va. 2010). *See* Motion p. 23. *DeCesare I* dismissed a claim for conspiracy for failure to adequately allege conspiracy. *DeCesare II* addresses the relator's amended complaint which resolved the prior inadequacies.

LabCorp now seeks to characterize its involvement with HDL and Singulex as "only [] preliminary high-level discussions." Motion pp. 23–24. However, this version of events does not comport with the facts alleged in the FAC. As stated above, LabCorp knowingly and physically participated in the HDL and Singulex fraud since mid-2010. Indeed, "from late 2010 until 2015, LabCorp performed tests for HDL" leading to invoices to "HDL for more than $7.6 million." FAC ¶ 388. In 2012, LabCorp "entered into a contract [] to perform some of the tests on the Singulex panel." *Id.* ¶ 436. Similarly, LabCorp and Singulex worked together, leading to invoices to Singulex of "more than $277,500," plus the value of referrals LabCorp received in order to continue drawing for Singulex. *Id.* ¶ 445.

In addition to these business relationships, Relators allege that since mid-2011 LabCorp had continuous high-level meetings with HDL and/or Singulex "to discuss collaboration with or the outright purchase of HDL's business," and to develop its relationship with Singulex. FAC ¶¶ 389–418. For example, in February 2013, discussions with HDL led to "a formal Non-Disclosure Agreement . . . and executives exchanged cell phone numbers in order to communicate orally[.]" *Id.* ¶ 395. Similarly, on March 1, 2013, a meeting between "top LabCorp executives" and HDL led to discussion of "mutually beneficial" arrangements, including "use of LabCorp's 'Patient Service Centers – phlebotomists." *Id.* ¶ 397. Through the end of March and into "mid-April 2013, Mallory and LabCorp executives discussed LabCorp's potential collaboration with and/or investment in HDL." FAC ¶ 399.

These discussions with Singulex and HDL were fruitful. By July 2013, "HDL was sending more than $100,000 a month in testing business to LabCorp." *Id.* ¶ 400. By November 2012, "Singulex budgeted $15,000 monthly for payments to LabCorp," *id.* ¶ 440, and in early 2013, "LabCorp and Singulex were collaborating to provide testing for employee health plans," *id.* ¶

441. And LabCorp was happy to keep drawing blood it knew was tainted by kickbacks—so long as it continued to receive a piece of the action. *Id.* ¶¶ 337, 437. Meetings and communications between LabCorp and its co-conspirators continued in August 2013, *id.* ¶¶ 401–02; September 2013, *id.* ¶¶ 403–04; October 2013, *id.* ¶ 405; November 2013, *id.* ¶ 407; January 2014, *id.* ¶ 409; March and April 2014, *id.* ¶ 411; and May 2014, *id.* ¶¶ 413–15.

Even after the OIG issued LabCorp's requested fraud alert, LabCorp's conspiracy with HDL and Mallory continued until July 28, 2014, when "King communicated to Mallory, for the first time, that LabCorp was no longer interested in collaborating with HDL." *Id.* ¶ 422. However, "LabCorp continued to do business with HDL and to bill HDL for testing it performed for HDL through March of 2015." *Id.* ¶ 423.

In summary, Relators' FAC alleges in detail LabCorp's agreement with HDL, including the who (several specific high level executives at LabCorp and HDL); the what (agreement to continue drawing blood for HDL so long as LabCorp received its cut from referrals, draw fees, or direct payments from HDL); the when (from late 2010 through March 2015); the where (a nationwide scheme facilitated by meetings at LabCorp and HDL headquarters, communications via cell phone and email); the how (by drawing the very blood samples needed for referrals to HDL and Singulex, who then billed for kickback tainted tests, all the while turning a blind eye to bad conduct or reporting "bad actors" depending on how it suited LabCorp); and the why (LabCorp's receipt of millions in EMV from their physician accounts receiving HDL and/or Singulex kickbacks, and at least $7.6 million directly from HDL for testing services), underlying the unlawful agreement between LabCorp and HDL.

Likewise, Relators' FAC alleges LabCorp's agreement with Singulex, including the who (LabCorp and Singulex); the what (agreement to draw blood for Singulex so long as LabCorp

received a referral and the separate business relationship with Singulex to perform a test in the Singulex panel); the when (starting at the latest in early 2012 through at least 2014); the how (LabCorp provided the phlebotomy and processing services); the where (a nationwide scheme); and the why (LabCorp's receipt of at least $277,500, LabCorp's measure of EMV, and the value of referrals under LabCorp's draw-for-referral policy).

These allegations identify who at LabCorp was involved, what LabCorp sought to gain (and actually did gain), and when the agreement was operative. *See, e.g. Ahumada*, 756 F.3d at 282. These allegations show that LabCorp assented to participation in the illegal scheme after knowing it amounted to an illegal agreement. *See DeCesare II*, 2011 WL 607390 at *7. LabCorp's agreements with HDL and Singulex are similar to the scheme in *Berkeley* that was "supercharged" by the parties' written agreement because the kickback scheme started before LabCorp's direct involvement, but flourished once LabCorp fully participated. *Berkeley*, 225 F. Supp. 3d at 497–98. Finally, an inference of LabCorp's agreement with Singulex and HDL is further supported by the ongoing communications between high-level executives at LabCorp, HDL, and Singulex. *SD3*, 801 F.3d at 432. Accordingly, Relators' conspiracy claims should not "be dismissed out of hand" as LabCorp requests.

(ii) LabCorp's faulty "report" of HDL/Singulex fraud demonstrates LabCorp's knowledge of fraudulent scheme and its intent to defraud the Government.

Throughout its four-year relationship with HDL and Singulex, LabCorp simultaneously played multiple angles – all driven by LabCorp's economic interests. For example, LabCorp purported to report its "competitors" through a request for a fraud alert, while at the same time conspiring with HDL and Singulex to generate millions in revenue for LabCorp. LabCorp now argues that its requests for fraud alerts somehow undermine a theory of conspiracy because "LabCorp reported [HDL's and Singulex's] conduct to the OIG." Motion p. 23. As described in

more detail below, LabCorp was fully involved in a conspiracy with HDL and Singulex to violate 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B). LabCorp's efforts to conceal its involvement in the conspiracy through the drafting and submission of bogus requests for fraud alerts does not mitigate its involvement in the fraudulent scheme. *See* 31 U.S.C. 3730(e)(4)(A) (requiring dismissal of publicly disclosed claims).

LabCorp's fraud alerts targeting HDL and Singulex demonstrate LabCorp's knowledge of the fraud, its efforts to profit from the fraudulent activity, and its intent to defraud the Government. FAC ¶¶ 68–70 (explaining LabCorp's knowledge of the scheme was shown through seemingly contradictory conduct). Since "at least the spring of 2010, LabCorp knew that HDL and Singulex were providing illegal inducements in the form of above-market [fees] to referring physicians and physician practices." FAC ¶ 262. Yet, LabCorp continued providing free blood draw and processing services "if there were also referrals being made to LabCorp." *Id.* ¶ 337. This overall scheme shows that LabCorp's conduct only *appeared* to be "inconsistent." In reality, LabCorp's conduct was entirely consistent with that of a duplicitous bad actor seeking to play two roles—courting HDL and Singulex while "turning a blind eye to HDL's fraud when it suited LabCorp's bottom line," *id.* ¶ 394, and simultaneously, half-heartedly, and belatedly reporting HDL and Singulex to the Government as "bad actors," after becoming involved in the conspiracy. *Id.* ¶ 393.

Relators have alleged that LabCorp had the specific intent to use the conspiracy to defraud the government. *See United States v. Berkeley Heartlab, Inc.*, 247 F. Supp. 3d 724, 733 (D.S.C. 2017) (denying motion to dismiss where agreement was entered with specific intent to defraud the government). In *DeCesare II*, the court held that a complaint sufficiently alleged intent to defraud when it alleged facts to show the defendant knew it was participating in an illegal referral network and continued participating. 2011 WL 607390 at *7. Here, LabCorp's requests for an OIG fraud

alert demonstrate it was fully aware of the unlawful conduct by HDL and Singulex. By continuing to participate in the unlawful scheme despite its knowledge, LabCorp demonstrated liability for defrauding the Government. The FAC provides more than sufficient allegations of intent.

E. Relators Request Leave to Amend to Address Any Insufficient Pleading Under Rule 12(b)(6) or 9(b)

As detailed above, LabCorp does not seek to dismiss Relators' FAC in its entirety. Relators have sufficiently alleged all bases of liability to survive a motion to dismiss. However, as to the claims that are subject to the instant motion, if the Court identifies any insufficiencies in the FAC, Relators respectfully request leave to amend their complaint to address any shortcomings. Courts should "freely give" plaintiffs leave to amend their complaint when "justice so requires." Fed. R. Civ. P. 15(a)(2). Where a plaintiff has not had a prior opportunity to amend a complaint in light of an order to dismiss on Rule 9(b) grounds, it is improper for the Court to deny leave to amend. *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 920 (4th Cir. 2012); *see also Forman v. Davis*, 371 U.S. 178, 182 (1962) (abuse of discretion for district court to deny leave to amend absent compelling justification). As this would be Relators' first opportunity to amend their complaint to address any deficiencies identified in the particularity of the allegations, the Court should grant the requested leave.

V. CONCLUSION

Relators' Fourth Amended Complaint provides ample legal and factual basis for each scheme of unlawful conduct that supports LabCorp's liability. Based on the allegations in the FAC, LabCorp is aware of the particular circumstances for which it will have to prepare a defense at trial, and the Court can determine that Relators have substantial evidence of those facts. Accordingly, the Court should deny LabCorp's Motion in its entirety. Alternatively, if the Court

identifies any deficiency in the pleadings, Relators request leave to amend to address such deficiencies.

This the 9th day of November, 2018.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically and will be served on all counsel of record via CM/ECF.

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This the 9th day of November, 2018.

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